



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-0895]

Issuance of Priority Review Voucher; Material Threat Medical Countermeasure Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a material threat medical countermeasure (MCM) product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the 21st Century Cures Act (Cures Act), authorizes FDA to award priority review vouchers to sponsors of approved material threat MCM product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. COMIRNATY (COVID-19 Vaccine, mRNA) was approved on August 23, 2020, and a license was issued to BioNTech Manufacturing GmbH. FDA has determined that COMIRNATY (COVID-19 Vaccine, mRNA) meets the criteria for a material threat MCM priority review voucher, which has been issued to BioNTech Manufacturing GmbH.

FOR FURTHER INFORMATION CONTACT: Myrna Hanna, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a material threat MCM priority review voucher to the sponsor of an approved material threat MCM product application. Under section 565A of the FD&C Act (21 U.S.C. 360bbb-4a), which was added by the Cures Act (Pub. L. 114-255), FDA will award priority review vouchers to sponsors of approved material threat MCM product applications that meet certain criteria upon approval of those applications. FDA has determined that COMIRNATY (COVID-19 Vaccine, mRNA)

meets the criteria for a material threat MCM priority review voucher, which has been issued to BioNTech Manufacturing GmbH. COMIRNATY is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

For further information about the material threat MCM Priority Review Voucher Program and for a link to the full text of section 565A of the FD&C Act, go to <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/mcm-related-counterterrorism-legislation>. For further information about COMIRNATY (COVID-19 Vaccine, mRNA) go to the Center for Biologics Evaluation and Research Approved Vaccine Products website at <https://www.fda.gov/vaccines-blood-biologics/vaccines/approved-vaccine-products>.

Dated: February 11, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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